DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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March 27, 2015

Olympus Surgical Technologies America
Gyrus ACMI, Inc.
Mary Anne Patella
Senior Specialist, Regulatory Affairs
136 Turnpike Road
Southborough, MA 01772-2104

Re: K143609
Trade/Device Name: EZDilate 3-Stage Balloon Dilatation Catheters
Regulation Number: 21 CFR§ 876.5365
Regulation Name: Esophageal dilator
Regulatory Class: II
Product Code: KNQ, FGE
Dated: January 16, 2015
Received: January 20, 2015

Dear Mary Anne Patella,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143609

Device Name
EZDilate 3-Stage Balloon Dilatation Catheters

Indications for Use *(Describe)*

The EZDilate 3-Stage Balloon Dilatation Catheters are indicated for use in adult populations to endoscopically dilate strictures of the alimentary tract. It is also indicated in adults for endoscopic dilatation of the Sphincter of Oddi with or without prior sphincterotomy.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary
Gyrus ACMI, Inc.
EZDilate 3-Stage Balloon Dilatation Catheter

General Information

Contract Manufacturer:	Vention Medical, Inc. 261 Cedar Hill Drive Marlborough, MA 01752 Phone: 508-481-6233
Establishment Registration Number:	3004734318
510(k) Submitter:	Gyrus ACMI, Inc. 136 Turnpike Rd. Southborough, MA 01772-2104
Establishment Registration Number:	3003790304
Contact Person:	Mary Anne Patella Senior Specialist Regulatory Affairs 508-804-2771 Maryanne.patella@olympus-osta.com
Date Prepared:	December 16, 2014

Device Description

Classification Name:	Catheter, Biliary, Diagnostic Dilator, Esophageal
CFR citation	21 CFR 876.5010, 876.5365
Procode	FGE, KNQ
Classification	Class II
Classification Panel	Gastroenterology/Urology
Trade Name:	*EZDilate 3-Stage Balloon Dilatation Catheter*
Generic/Common Name:	Balloon Dilation Catheter

Predicate Devices

Boston Scientific CRE Dilatation Balloon	K112994

Product Description

The EZDilate 3-Stage Balloon Dilatation Catheter consists of a semi-compliant nylon blow molded balloon; and, a shaft that communicates a fluid passage for expansion and collapse of the balloon portion, operated by an inflation device.
The EZDilate Wire Guided Balloon is designed to be used with a 0.035 in. (0.89mm) guidewire and has a wire lumen sized appropriately. Each balloon catheter is packaged with a soft tip 0.035 in. (0.89mm) guidewire pre-loaded into the guidewire lumen. All wire-guided balloons with have lengths of 5.5cm and a catheter length of 240cm.
The balloon is inflated with a 60cc inflation device, which will be sold separately. The suggested inflation device is manufactured by Atrion (K032840).

Technological Characteristics

The EZDilate 3-StageWire Guided Balloon Dilatation Catheter is a reinforced catheter attached to a distal dilatation balloon. The semi-compliant balloon allows for a progressive radial expansion through three target sizes using one balloon. A silicone coating applied to the balloon increases ease of insertion, positioning of the balloon within the alimentary tract, and device removal.

Material

The EZDilate – Wire Guided 3-stage balloon dilatation catheter is a dual lumen catheter with a distal end comprising a nylon balloon and a proximal end comprising an inflation port and guidewire port. . The balloon tube, guidewire tube, and bifurcation hub are all constructed of Pebax. A silicone coating is applied to the balloon. A PTFE coated guidewire is pre-loaded into the guidewire lumen.

Intended Uses

The EZDilate 3-Stage Balloon Dilatation Catheters are indicated for use in adult populations to endoscopically dilate strictures of the alimentary tract. It is also indicated in adults for endoscopic dilatation of the Sphincter of Oddi with or without prior sphincterotomy.

Compliance to Voluntary Standards

The design of the proposed device complies with the following standards:

ISO 594-1:1986
ISO 594-2: 1998
ISO 10993-1, 2009
ISO 10993-5, 2009

ISO 10993-7:2008(R)2012
ISO 10993-10, 2010
ANSI/AAMI/ISO 11135-1, 2007
ISO 1138-2:2006
ISO 14971, 2012
ISTA P2A, 2011
ASTM D4169-09
ASTM F2096-11
ASTM F88/F88M:2009
ASTM F1886/F1886M:2009
ASTM F1980-07 (2011)

Summary of Sterilization and Shelf Life Discussion

The EZDilate 3-Stage Balloon Dilatation Catheter is delivered in a sterile state and is intended for single patient use only. The sterilization method used is ethylene oxide. Six month shelf life data will be submitted to support the 510(k) submission; the product will be launched with a shelf life of three (3) years.

Summary of Performance Testing

During design verification, the output of the design process was evaluated against the physical and performance specifications. In general, the evaluation compared the function of the EZDilate 3-Stage Balloon Dilatation Catheter against these specified requirements.

- First Article Inspection (Dimensional Measurements)
- Tensile Testing
- Fatigue Testing
- Luer Gauging Test
- Balloon Working Length
- Tip Stiffness Testing
- Compliance Testing
- Balloon Burst Testing
- Balloon Insertion Force Testing
- Balloon Friction Testing
- Balloon Deflation Testing
- Balloon Endoscope Compatibility Testing

Substantial Equivalence

The proposed EZDilate 3-Stage Balloon Dilatation Catheter has the same intended use, design, and scientific technology as the Predicate Boston Scientific CRE

Dilatation Balloon (K112994). Both devices are of similar design and there were no new issues of safety or effectiveness with the proposed device.

Conclusion:

In summary, the EZDilate 3-Stage Balloon Dilatation Catheter is substantially equivalent to the predicate devices and presents no new questions of safety or efficacy.